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10/764,857	01/26/2004	Arthur Zaks	763510-3	9797

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,857	ZAKS, ARTHUR	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *22 November 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-11 are pending and are considered herewith.

Information Disclosure Statement

The Information Disclosure Statement submitted on November 22, 2004 is acknowledged.

Specification

1. The use of the trademark AMBIEN® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

2. Claim 10 is objected to because of the following informalities: typographical errors. "Ritilin" has been misspelled and should be corrected to ritalin. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inducing pain relief with zolpidem, does not reasonably provide enablement for inducing pain relief with any other imidazo[1,2-a]pyridine derivative. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to a method of inducing pain relief comprising administering an imidazo[1,2-a]pyridine.

(2). ***State of the Prior Art***:

The skilled artisan has recognized various derivatives of imidazo[1,2-a]pyridine, namely 2-(iodophenyl)-imidazo[1,2-a]pyridines and 2-aryl substuted imidazo[1,2-a]pyridines (page 2, lines 11 and 18 of the specification).

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the art of pain relief is extremely high.

(4). ***Predictability of the Art***:

The composition of any imidazo[1,2-a]pyridine is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a method of inducing pain relief comprising administering an imidazo[1,2-a]pyridine.

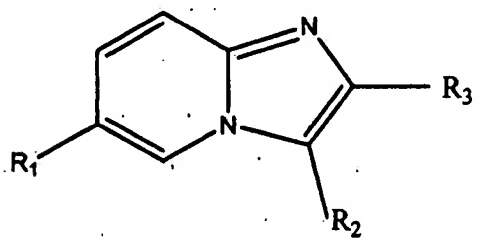
(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to the method for inducing pain relief comprising administrating any other imidazo[1,2-a]pyridine of the instant invention is limited.

The disclosure of the method for inducing pain relief comprising administrating zolpidem is adequate (example on pages 10-11).

(7). ***Working Examples***:

The working examples in the specification show pain abatement using zolpidem (page 10, lines 20-22). The only imidazo[1,2-a]pyridine derivative used, zolpidem, has a chemical name of N,N,6-trimethyl-2-p-tolyl-imidazo[1,2-a]pyridine-3-acetamide (page 3, lines 27-28). Zolpidem is a imidazol[1,2-a]pyridine of the formula:



where R_1 is an alkyl, R_2 is a methylamino, and R_3 is an alkylphenyl (page 2, lines 22-24; and page 3, line 1).

Furthermore, the different imidazo[1,2-a]pyridine derivatives have different structures and thus different chemical and physical properties and efficacies. Therefore, the invention may not work with all the imidazo[1,2-a]pyridine derivatives herein claimed.

Thus, the working examples show how to induced pain relief with an imidazo[1,2-a]pyridine derivative where R_1 is an alkyl, R_2 is a methylamino, and R_3 is an alkylphenyl, namely zolpidem, but not any other imidazo[1,2-a]pyridine derivative.

Note that lack of a working example to prevent, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of a any imidazo[1,2-a]pyridine derivative. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any imidazo[1,2-a]pyridine derivative having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Meisler (Journal of Women's Health & Gender-Based Medicine. 2000. Vol. 9, No. 5, pp. 477-482).

Meisler teaches treatment for women suffering from chronic fatigue syndrome, who oftentimes also struggle with chronic pain, comprising zolpidem and provigil (page 477 and 479-480).

It is noted that zolpidem is well known in the art under the trademark AMBIEN® and has the chemical name of N,N,6-trimethyl-2-p-tolyl-imidazo[1,2-a]pyridine-3-acetamide L-(+)-tartrate.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meisler (Journal of Women's Health & Gender-Based Medicine. 2000. Vol. 9, No. 5, pp. 477-482) as applied to claims 1-3, 6, and 9-11 above, in view of Holman (US 2002/0165246).

Meisler does not teach oral and topical administration of zolpidem.

Holman teaches the oral and topical administration of zolpidem for sleep restoration (page 4, paragraph [0048]; and page 5, paragraph [0056]).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the compositions of zolpidem and provigil of Meisler to restore sleep because the composition of zolpidem of Holman are used for sleep restoration and according to Meisler, the sleep medication zolpidem is used to sufferers of chronic fatigue syndrome who also struggle with chronic pain.

The motivation to combine the compounds of Meisler to the compounds of Holman is that the compounds of Holman are used for sleep restoration.

6. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meisler (Journal of Women's Health & Gender-Based Medicine. 2000. Vol. 9, No. 5, pp. 477-482) as applied to claims 1-3, 6, and 9-11 above, in view of Malin et al. (US 5,084,007), Kaplan et al. (US 4,501,745), and Kaplan et al. (US 4,382,938).

Meisler does not teach pain caused by metastatic cancer.

Malin et al. teach derivatives of imidazo[1,2-A]pyridine can be to treat chronic pain resulting from terminal cancer (column 3, line 53; and column 7, line 42).

It is noted that "terminal cancer" is well known in the art to be metastatic.

To a person of skill in the art at the time of the invention, it would have been obvious to employ the compositions of zolpidem and provigil of Meisler to treat pain resulting from metastatic cancer because the compounds of Malin et al. are imidazo[1,2-a]pyridine derivatives and according to Malin et al., imidazo[1,2-a]pyridine derivatives can be used to treat pain resulting from terminal cancer.

The motivation to combine the compounds of Meisler to the compounds of Malin et al. is that the compounds of Malin et al. are imidazo[1,2-a]pyridine derivatives and that such imidazo[1,2-a]pyridine derivatives treat pain resulting from terminal cancer.

Regarding the imidazo[1,2-A]pyridine derivative in Malin et al., it is noted that Malin et al. refer to US Patent No. 4,501,745 to Kaplan et al., which teach a different imidazo[1,2-a]pyridine than the instant application. However, US Patent No. 4,382,938 to Kaplan et al. teach the same imidazo[1,2-a]pyridine of the instant application. It is noted that it would be obvious to one skilled in the art at the time of the invention to use the imidazo[1,2-a]pyridine derivatives of 4,382,938 in lieu of the imidazo[1,2-A]pyridine derivatives of 4,501,745 because both posses anxiolytic, antianoxic, sleep-inducing, hypnotic, and anticonvulsant properties (abstract from both Kaplan et al. patents).

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER